DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 10, 2014

Vilex in Tennessee Inc.
% Mr. Abraham Lavi, PhD
Vilex, Inc.
8374 Market Street, Suite 167
Lakewood Ranch, Florida 34202

Re: K141937
Trade/Device Name: Trident™ Fusion Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 23, 2014
Received: July 25, 2014

Dear Dr. Lavi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VILEX Inc.
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INDICATIONS FOR USE

510(k) NUMBER: K141937

DEVICE NAME: Trident™ Fusion Implant

INDICATIONS FOR USE:

The Trident Fusion Implant has the following Indications for Use:
Fixation of osteotomies and reconstruction of the lesser toes and lesser fingers following correction procedures for hammertoe, claw toe, mallet toe, and other deformities of the feet and hands.

Prescription Use _____X_____
(Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (DOE)

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510(k) Summary
Trident Fusion Implant
K141937

Sponsor:	Vilex in Tennessee, Inc
Contact Person:	Abraham Lavi
Date Prepared:	September 4, 2014
Trade Name:	Trident Fusion Implant
Common Name:	Threaded metallic bone fixation fastener
Classification Name:	21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener
Product Code:	HWC/ Orthopedics, Class II
Predicate Devices:	K111536 DigiFuse, MetaSurg K120645, K101165 Pro-Toe, Wright Medical K022599 K Wire, Newdeal K052736 K-Wire, Arthrex
Description of Device:	The Vilex Trident Fusion Implant is a single-piece cannulated bone screw intended for the fixation of PIP joints in lesser toes and digits. The device is offered straight or with a 10^{o} bend at the joint. It is available in either stainless steel or titanium.
Indications for Use:	The Trident Fusion Implant has the following Indications for Use: Fixation of osteotomies and reconstruction of the lesser toes and lesser fingers following correction procedures for hammertoe, claw toe, mallet toe, and other deformities of the feet and hands.
Technological Characteristics:	The technological characteristics for the Trident Fusion Implant are the same as the characteristics of the predicate devices. All of the sizes included in the Vilex Trident Fusion Implant system are within the range of offerings of the predicate devices and the designs of the Trident devices are similar to the predicate devices. The materials used to manufacture the Trident Fusion Implants are the same as those used to manufacture the predicate devices.
Substantial Equivalence	The design features of the Trident Fusion Implant are substantially equivalent to the design features of other predicate devices previously cleared for market. The methods used to establish equivalence are indications for use, material of construction, sizes, and shapes. The safety and effectiveness of the Trident Fusion Implant are adequately supported by the substantial equivalence information, material information and analysis data provided within this Premarket Notification. Therefore, it is concluded that the Trident Fusion Implants are substantially equivalent to the noted predicate devices.

510(k) Summary
Triden Fusion Implant

Conclusions:	While the Trident Fusion Implants are not identical to the predicate devices, any differences that may exist do not significantly affect device safety and effectiveness. In addition, the differences do not add new or increased risks and complications. Therefore, it is concluded that the Trident Fusion Implants are substantially equivalent to the predicate devices as outlined previously and should not render the subject device NSE.